## UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

BRIAN J. KIRKPATRICK, an individual,

Plaintiff,

Case No.

VS.

JURY TRIAL DEMANDED

COOK INCORPORATED, COOK MEDICAL INCORPORATED, COOK GROUP INCORPORATED, and COOK MEDICAL, LLC

Defendants.

#### **COMPLAINT**

Plaintiff Brian J. Kirkpatrick, by and through undersigned attorneys, hereby sues Cook Incorporated, Cook Medical Incorporated, Cook Group Incorporated, and Cook Medical, LLC, and alleges as follows:

### **PARTIES**

- 1. Plaintiff Brian J. Kirkpatrick (hereinafter "Plaintiff") at all times relevant to this action resided in, continues to reside in, and is a citizen of Norfolk County, Massachusetts.
- 2. Defendant Cook Incorporated was and is an Indiana corporation with its principal place of business located at 750 Daniels Way, Bloomington, Indiana 47402. At all times relevant to this action, Cook Incorporated designed, set specifications, manufactured, prepared, compounded, assembled, processed, promoted, marketed, distributed, and/or sold the inferior vena cava filter ("IVC Filter") known as the Celect Platinum <sup>TM</sup>

Vena Cava Set (hereinafter "Cook filter") to be implanted in patients throughout the United States, including Massachusetts. At all times relevant hereto, Defendant Cook Incorporated was registered to do business in Massachusetts, engaged in business in Massachusetts, has conducted substantial business activities and derived substantial revenue from within the Commonwealth of Massachusetts. This Defendant has also carried on solicitations or service activities in Massachusetts.

- 3. Defendant Cook Medical Incorporated is an Indiana limited liability corporation and a wholly owned subsidiary of Defendant Cook Incorporated with its principal place of business located at 1025 West Acuff Road, Bloomington, IN, 47404. Defendant Cook Medical Incorporated was and is an Indiana limited liability corporation authorized and/or doing business in the Commonwealth of Massachusetts. At all times relevant to this action, Cook Medical Incorporated designed, set specifications, manufactured, prepared, compounded, assembled, processed, promoted, marketed, distributed, and/or sold the inferior vena cava filter ("IVC Filter") known as the Celect Platinum<sup>TM</sup> Vena Cava Set to be implanted in patients throughout the United States, including Massachusetts. At all times relevant hereto, Defendant Cook Medical Incorporated was engaged in business in Massachusetts has conducted substantial business activities and derived substantial revenue from within the Commonwealth of Massachusetts. This Defendant has also carried on solicitations or service activities in Massachusetts.
- 4. Defendant Cook Group Incorporated was and is an Indiana corporation having its principal place of business located at 750 Daniels Way, Bloomington, Indiana 47402. At all times relevant to this action, Cook Group Incorporated designed, set

specifications, manufactured, prepared, compounded, assembled, processed, promoted, marketed, distributed, and sold the inferior vena cava filter ("IVC Filter") known as the Celect Platinum <sup>TM</sup> Vena Cava Set to be implanted in patients throughout the United States, including Massachusetts. At all times relevant hereto, Defendant Cook Group Incorporated was engaged in business, has conducted substantial business activities, and derived substantial revenue from within the Commonwealth of Massachusetts. This Defendant has also carried on solicitations or service activities in Massachusetts.

5. Defendant Cook Medical, LLC was and is an Indiana limited liability corporation with its principal place of business located at 750 Daniels Way, Bloomington, Indiana 47402 with its sole member being Cook Incorporated and maintains its principal place of business located at 750 Daniels Way, Bloomington, Indiana 47402. At all times relevant to this action, Cook Medical, LLC designed, set specifications, manufactured, prepared, compounded, assembled, processed, promoted, marketed, distributed, and/or sold the inferior vena cava filter ("IVC Filter") known as the Celect Platinum TM Vena Cava Set to be implanted in patients throughout the United States, including Massachusetts. At all times relevant hereto, Cook Medical, LLC. was registered to do business with the Commonwealth of Massachusetts. At all times relevant hereto, Defendant Cook Medical LLC was engaged in business in Massachusetts, has conducted substantial business activities and derived substantial revenue from within the Commonwealth of Massachusetts. This Defendant has also carried on solicitations or service activities in Massachusetts.

- 6. Defendants Cook Incorporated, Cook Incorporated a/k/a Cook Medical Incorporated, Cook Group Incorporated, and Cook Medical, LLC shall be referred to herein individually by name or collectively as the "Cook Defendants."
- 7. At all times alleged herein, Cook Defendants include and included any and all parent companies, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors, and assigns and their officers, directors, employees, agents, representatives, and any and all other persons acting on their behalf.
- 8. At all times herein mentioned, each of the Cook Defendants were the agents, servants, partners, predecessors in interest, and joint venturers of each other, and were at all times operating and acting with the purpose and scope of said agency, service, employment, partnership, joint enterprise, and/or joint venture.
- 9. At all times herein mentioned, each of the Cook Defendants were the agents, servants, partners, predecessors in interest, and joint venturers of each other, and were at all times operating and acting with the purpose and scope of said agency, service, employment, partnership, joint enterprise, and/or joint venture.

## **JURISDICTION AND VENUE**

- 10. Jurisdiction is proper in this court under 28 U.S.C.§ 1332(a)(1) because the Plaintiff and the Defendants are citizens of different states, and the amount in controversy exceeds seventy-five thousand dollars (\$75,000.00), exclusive of interest and costs.
- 11. Venue is proper in this court under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claim occurred within this judicial district

and the Defendants regularly conduct business in this district.

# GENERAL ALLEGATIONS INFERIOR VENA CAVA FILTERS GENERALLY

- 12. IVC filters first came on to the medical market in the 1960s. Over the years, medical device manufacturers have introduced several different designs of IVC filters.
- 13. An IVC filter is a device that is intended to filter or "catch" blood clots that travel from the lower portions of the body to the heart and lungs. IVC filters are designed to be implanted, either permanently or temporarily, in the IVC.
- 14. The IVC is a vein that returns blood to the heart and lungs from the lower portions of the body. In certain people, for various reasons, blood clots travel from the vessels in the legs and pelvis, through the vena cava and into the lungs. Oftentimes, these blood clots develop in the deep leg veins, a condition called "deep vein thrombosis" or "DVT." Once blood clots reach the lungs, they are considered "pulmonary emboli" or "PE." Pulmonary emboli present risks to human health.
- 15. People at risk for DVT/PE can undergo medical treatment to manage the risk. For example, a doctor may prescribe medications like Heparin, Warfarin, or Lovenox to regulate the clotting factor of the blood. In some people who are at high risk for DVT/PE, or who cannot manage their conditions with medications, physicians may recommend surgically implanting an IVC filter to prevent thromboembolitic events.
- 16. The first IVC filters sold were permanent filters. These devices were designed to be left in a patient's IVC permanently and have long-term follow-up data (of up

to 20 years and longer) demonstrating their risks and the frequency of occurrence of such risks, which is relatively low.

17. Beginning in 2003, manufacturers also began marketing what are known as "optional" or "retrievable" filters. These filters were designed so that, in theory, they can be surgically removed from a patient after implantation, presumably after the risk of PE has subsided. These optional or retrievable filters are sold as permanent filters with an option to remove them.

#### **GENERAL FACTUAL ALLEGATIONS**

- 18. Plaintiff brings this case against the Cook Defendants because of the serious, life-threatening injury he has suffered as a result of the Cook Defendants' surgically implanted medical device, the Cook Celect Platinum filter, that was implanted by Aqueel M. Siddiqui, M.D. at Signature Healthcare Brockton in Brockton, Massachusetts on February 22, 2017.
- 19. Cook Defendants design, research, develop, manufacture, test, market, advertise, promote, distribute, and sell IVC filters, which are marketed and sold as both permanent and retrievable devices, purportedly to prevent recurrent pulmonary embolism.

  One such product is the Cook Celect Platinum IVC filter at issue in this case.
- 20. To date, there is no evidence to support the notion that IVC filters offer any clinical benefit to patients.
- 21. Cook Defendants sought Food and Drug Administration ("FDA") clearance to market the Cook Celect Platinum filter device and/or its components under Section 510(k) of the Medical Device Amendment.

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- 22. On or about July 3, 2012, Defendants obtained FDA clearance to market the Cook Celect Platinum filter under Section 510(k) of the Medical Device Amendment.
- 23. Section 510(k) allows marketing of medical devices if the manufacturer claims the device is substantially equivalent to other legally marketed predicate devices, without formal review of the safety or efficacy of said device. The Cook Defendants claimed that the Celect Platinum filter was substantially equivalent to the Cook Celect IVC filter, a medical device cleared by the FDA under the Section 510k process on April 20, 2007.
- 24. An IVC filter, like the Cook Celect Platinum filter, is a device ostensibly designed and intended to filter blood clots (called "thrombi") that would otherwise travel from the lower portions of the body to the heart and lungs, resulting in a pulmonary embolism (PE). IVC filters are marketed as being safe to implant, either temporarily or permanently, within the vena cava.
- 25. The inferior vena cava is a vein that returns blood to the heart from the lower portions of the body. In certain people, and for various reasons, thrombi travel from vessels in the legs and pelvis, through the vena cava and into the heart and lungs. These thrombi can develop in the deep leg veins. This condition is called "deep vein thrombosis" or DVT. If the thrombi reach the lungs they are considered "pulmonary emboli" or PE.
- 26. The Celect Platinum filter is a retrievable filter and is alleged by Cook as being substantially similar to the Cook Defendants' Celect filter, its predicate device.

- 27. The Celect Platinum filter has four (4) anchoring legs, or struts, for fixation within the IVC and eight (8) independent secondary struts claimed by Cook to improve self-centering and clot trapping.
- 28. On or about February 22, 2017, Plaintiff was implanted with a Cook Celect Platinum filter at Signature Healthcare Brockton in Brockton, Massachusetts. The Cook Celect Platinum filter placed in Plaintiff was marketed and sold as appropriate for use as either a retrievable or permanent filter.
- 29. Plaintiff has suffered serious injury as a result of the implantation of the Cook Celect Platinum filter. Specifically, multiple prongs of Plaintiff's Cook Celect Platinum filter have perforated his IVC, with one prong abutting his duodenum. Plaintiff's Cook Celect Platinum filter has also migrated, with the apex above the level of his renal veins. Plaintiff is at risk for future progressive perforations by the Celect Platinum filter which could further injure adjacent organs, blood vessels, and structures, as well as fracturing of the IVC filter and migration of the Celect Platinum filter or pieces thereof. The Plaintiff faces numerous health risks, including the risk of death. Plaintiff will require ongoing medical care and monitoring for the rest of her life. It is unknown if the filter can be retrieved by any means other than an open surgical procedure.
- 30. At all relevant times hereto, Cook Defendants' were engaged in the business of designing, manufacturing, fabricating, promoting, advertising, selling and distributing the Celect Platinum IVC Filter for ultimate sale to, and implantation in, patients like Plaintiff. Defendants designed, manufactured, fabricated, and sold the IVC filter to

hospitals and physicians knowing that they would be sold to and implanted in patients like Plaintiff.

- 31. Cook Defendants' Celect Platinum IVC Filter was expected to and did reach the Plaintiff and the public without substantial change in its condition as manufactured and sold by Cook Defendants. In light of the defect described herein, at the time the IVC filter reached the Plaintiff it was in a condition not contemplated by any reasonable person among the expected users of the device, and was unreasonably dangerous to the expected users of the device when used in reasonably expected ways of handling or consumption.
- 32. The Celect Platinum IVC Filter designed, manufactured and sold by the Cook Defendants to patients, like the Plaintiff, was in a defective condition unreasonably dangerous to any user or consumer of the device, and plaintiff was in the class of persons that the Cook Defendants should have reasonably foreseen as being subject to the harm caused by the filter's defective condition.
- 33. Plaintiff used the Cook Defendants' Celect Platinum IVC Filter in the manner in which the device was intended to be used.
- 34. Plaintiff was not aware and could not in the exercise of reasonable care have discovered the defective nature of the device nor could he have known that Cook Defendants designed, manufactured or fabricated the filter in a manner that would increase the risk of bodily injury to its recipients.
- 35. At all times relevant hereto, the Cook Celect Platinum filter was widely advertised and promoted by the Cook Defendants as safe and effective for prevention of recurrent pulmonary embolism.

- 36. At all times relevant to this complaint, the Cook Defendants knew or should have known that the Cook Celect Platinum IVC filter was defective and knew that defect was attributable to the design's failure to withstand the normal anatomical and physiological loading cycles exerted in vivo.
- 37. The Cook Defendants failed to disclose to physicians, patients, or Plaintiff that its retrievable IVC filters, including the Cook Celect Platinum filter, were subject to perforation through the IVC wall, fracture, and migration or the appropriate degree of risk of perforation and damage to the vena cava wall and surrounding organs, blood vessels, and structures.
- 38. At all times relevant hereto, the Cook Defendants continued to promote Cook's retrievable IVC filters, including the Cook Celect Platinum filter, as safe and effective even though the clinical trials that had been performed were not adequate to support long- or short-term safety or efficacy.
- 39. At all times relevant to this cause of action, and as detailed herein, the Cook Defendants negligently provided Plaintiff, Plaintiff's health care providers, and the general medical community with false or incorrect information, or omitted or failed to disclose material information, concerning Cook IVC filters and the Cook Celect Platinum filter; including, but not limited to, misrepresentations relating to the safety, efficacy, failure rate and approved uses of the Cook IVC filter.
- 40. The Cook Defendants falsely represented to Plaintiff, his physicians, and other members of the general public, that the Cook Celect Platinum IVC filter:
  - a. Was proven to be hemodynamically effective;

- b. Has been proven to effectively prevent pulmonary embolism;
- c. Was self-centering and offered efficient clot trapping;
- d. Was designed to minimize the most common filter complications;
- e. The anchors on the filter created secure atraumatic attachments to the caval wall;
- f. Provided enhanced retrievability giving an extended time for retrieval; and
- g. Could safely stay in place permanently in the body.
- 41. In the Clinical Study section of the Instructions for Use provided to the physicians who were implanting the Cook Celect IVC filter, including the filter implanted in the Plaintiff, the Cook Defendants states a clinical study involved a 74 patient cohort, with follow-up conducted at 1 month (60 of 69 possible patients), 3 months (50 of 58 possible patients) and 6 months (37 of 41 possible patients) consisting of clinical exam and imaging by X-ray and duplex ultrasound, no device related major adverse events (defined as hemorrhage, perforation, death, occlusion, filter fracture or significant filter migration) occurred.
- 42. The representations by the Cook Defendants were, in fact, false. The true facts were that the Cook Celect Platinum IVC filter is not safe for long term/permanent surgical implantation for said purposes, it has not been proven the filter effectively prevents pulmonary embolism; the filter presents a high risk of perforation through the caval wall, the filter has a high risk for fracture, and the filter is not safe for permanent placement in the body. In the clinic study that was presented to physicians through the instructions for use, the IFU gives a false sense of safety by reporting on a subset of OUS patients regarding high rates of successful retrieval rates and no complications, which has been shown to be

incorrect. The retrieval rates listed give a false sense of safety when the OUS study did not address safety, and falsified complication and perforation rates. The Celect Platinum filter was and is, in fact, dangerous to the health and body of Plaintiff.

- 43. The information distributed by the Cook Defendants to the public, the medical community and Plaintiff's health care providers, including reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, was false and misleading, and contained omissions and concealment of truth about the dangers of the use of the Cook IVC filters, including the Cook Celect Platinum Filter.
- 44. The Cook Defendants made the foregoing misrepresentations knowing that they were false and/or without reasonable basis in fact. These materials included instructions for use and warning document that was included in the packaging of the Cook Celect Platinum filter that was implanted in Plaintiff.
- 45. The Cook Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff's health care providers; to gain the confidence of the public and the medical community, including Plaintiff's health care providers; to falsely assure them of the quality of the Cook IVC filters, including the Celect Platinum IVC filter and its fitness for use; and to induce the public and the medical community, including Plaintiff's healthcare providers to request, recommend, prescribe, implant, purchase, and continue to use Cook IVC filters, including the Cook Celect Platinum filter.

- 46. Cook Defendants concealed the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Cook retrievable IVC filters, including the Cook Celect Platinum filter, as aforesaid.
- 47. The failure of the Cook filter is attributable in part to the fact that the Cook retrievable IVC filters, including the Cook Celect Platinum filter, suffer from a design defect causing the filters to be unable to withstand the normal anatomical and physiological loading cycles exerted in vivo.
- 48. At all times relevant hereto, the Cook Defendants failed to provide sufficient warnings and instructions that would have put Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the Cook Celect Platinum filter, including, but not limited to, the design's failure to withstand the normal anatomical and physiological loading cycles exerted in vivo.
- 49. The Cook Celect Platinum filter was designed, manufactured, distributed, marketed, promoted, sold, and/or supplied by Cook Defendants and was marketed while defective due to the inadequate warnings, instructions, labeling, and/or inadequate testing in light of Cook Defendants' knowledge of the product's failure and serious adverse events.
- 50. At all times relevant hereto, the officers and/or directors of the Cook Defendants named herein participated in, authorized, and/or directed the production and promotion of the aforementioned products when they knew or should have known of the hazardous and dangerous propensities of said products, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by Plaintiff.

#### **CORPORATE/VICARIOUS LIABILITY**

- 51. At all times herein mentioned, the Cook Defendants were agents, servants, partners, aiders and abettors, co-conspirators, and/or joint venturers, and were at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy, and/or joint venture and rendered substantial assistance and encouragement to each other, knowing that their collective conduct constituted a breach of duty owed to the Plaintiff.
- 52. There exists and, at all times herein mentioned, there existed a unity of interest in ownership between the Cook Defendants such that any individuality and separateness between them have ceased and these Defendants are alter egos. Adherence to the fiction of the separate existence of these Defendants as entities distinct from each other will permit an abuse of the corporate privilege and would sanction a fraud and/or would not promote injustice.
- 53. At all times herein mentioned, the Cook Defendants were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing, and/or advertising for sale, and selling products for use by the Plaintiff. As such, each Defendant is individually, as well as jointly and severally, liable to the Plaintiff for Plaintiff's damages.
- 54. At all times herein mentioned, the officers and/or directors of the Cook Defendants named herein participated in, authorized and/or directed the production,

marketing, promotion and sale of the aforementioned products when they knew, or with the exercise of reasonable care and diligence should have known, of the hazards and dangerous propensities of said products, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by the Plaintiff.

## COUNT I <u>NEGLIGENCE</u>

- 55. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 16 52 as though fully set forth herein.
- 56. At all times relevant to this cause of action, the Cook Defendants were in the business of designing, developing, setting specifications, manufacturing, marketing, promoting, selling, and distributing Cook IVC filters including the Cook Celect Platinum IVC filter.
- 57. The Cook Defendants designed, manufactured, marketed, inspected, labeled, promoted, distributed and sold the Cook Celect Platinum filter that was implanted in Plaintiff.
- 58. The Cook Defendants had a duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of Cook IVC filters, including the Celect Platinum filter, so as to avoid exposing others to foreseeable and unreasonable risks of harm.
- 59. The Cook Defendants knew or reasonably should have known that the Cook Celect Platinum filter was dangerous or was likely to be dangerous when used in its intended or reasonably foreseeable manner.

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- 60. At the time of manufacture and sale of the Cook Celect Platinum filter (2012 until present), the Cook Defendants knew or should have known that the Cook Celect Platinum filter was designed and manufactured so as to present an unreasonable risk of the device tilting and/or perforating the vena cava wall.
- of 1. At the time of manufacture and sale of the Cook Celect Platinum filter (2012 until present), the Cook Defendants knew or should have known that using the Cook Celect Platinum filter in its intended use or in a reasonably foreseeable manner created a significant risk of a patient suffering severe health side effects, including, but not limited to: hemorrhage; pericardial effusion; cardiac tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; perforations of tissue, vessels, and organs; and other severe personal injuries and diseases, which are permanent in nature, including, but not limited to, death, physical pain and mental anguish, scarring and disfigurement, diminished enjoyment of life, continued medical care and treatment due to chronic injuries/illness proximately caused by the device; and the continued risk of requiring additional medical and surgical procedures including general anesthesia, with attendant risk of life threatening complications.
- 62. The Cook Defendants knew or reasonably should have known that consumers of the Cook Celect Platinum filter would not realize the danger associated with using the device in its intended use and/or in a reasonably foreseeable manner.
- 63. The Cook Defendants breached their duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling,

promotion, distribution and sale of the Cook Celect Platinum filter in, among others, the following ways:

- a. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking safety measures to reduce or avoid harm;
- b. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other devices available for the same purpose;
- c. Failing to use reasonable care in manufacturing the product and producing a product that differed from their design or specifications or from other typical units from the same production line;
- d. Failing to use reasonable care to warn or instruct, including pre and post-sale, Plaintiff, Plaintiff's physicians, Plaintiff's agents or the general health care community about the Cook Celect Platinum filter's substantially dangerous condition or about facts making the product likely to be dangerous;
- e. Failing to perform reasonable pre and post-market testing of the Cook Celect Platinum filter to determine whether or not the product was safe for its intended use;
- f. Failing to provide adequate instructions, guidelines, and safety precautions, including pre and post-sale, to those persons to whom it was reasonably foreseeable would prescribe, use, and implant the Cook Celect Platinum filter;
- g. Advertising, marketing and recommending the use of the Cook Celect Platinum filter, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with and inherent in the use of the Cook Celect Platinum filter;
- h. Representing that the Cook filter was safe for its intended use when in fact, the Cook Defendants knew and should have known the product was not safe for its intended purpose;
- i. Continuing manufacture and sale of the Cook Celect Platinum filter with the knowledge that said product was dangerous and not reasonably safe;
- j. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the Cook Celect Platinum filter so as to avoid the risk of serious harm associated with the use of the Cook Celect Platinum filter;

- k. Advertising, marketing, promoting and selling Cook Celect Platinum filter for uses other than as approved and indicated in the product's label;
- 1. Failing to establish an adequate quality assurance program used in the manufacturing of the Cook Celect Platinum filter; and,
- m. Failing to establish and maintain an adequate post-market surveillance program.
- n. Failing to conduct patient studies to determine whether the Cook Celect Platinum filter offers a clinical benefit to patients.
- o. Upon learning that IVC filters do not provide any clinical benefit to patients, defendants continued to sell its IVC filters, failed to pull them off the market, failed to notify the medical community to stop implanting its filters and failed to notify patients implanted with filters to have them removed.
- 64. A reasonable manufacturer, distributor, or seller under the same or similar circumstances would not have engaged in the aforementioned acts and omissions.
- 65. As a direct and proximate result of the foregoing negligent acts and omissions by the Cook Defendants, Plaintiff has suffered a serious medical complication for which the solution and ultimate economic loss is yet to be determined.

### COUNT II BREACH OF IMPLIED WARRANTY

- 66. Plaintiff realleges and incorporates by reference each and every allegation contained in paragraphs 16 52 as though fully set forth herein.
- 67. Prior to, on, and after the dates during which Plaintiff was implanted with the Filter, and at all relevant times, Cook Defendants, and each of them, had knowledge of the purpose for which the Filter was to be used, and represented it to be in all respects safe, effective, and proper for such purpose.
  - 68. Cook Defendants impliedly warranted that their Celect Platinum IVC Filter

which it designed, manufactured, fabricated, promoted and sold to the public and the Plaintiff were merchantable and fit and safe for their intended purpose and ordinary use. Defendants further impliedly warranted that the Celect Platinum IVC filter which Cook Defendants designed, manufactured, fabricated, promoted and sold to the public and the Plaintiff, was fit for the particular purpose to filter or "catch" blood clots that travel from the lower portions of the body to the heart and lungs.

- 69. Implied warranty of merchantability for the Cook Celect Platinum filter is contained within M.G.L. c. 93A.
- 70. Said implied warranty is made to consumers, such as Plaintiff, his treating physicians and medical professionals.
- 71. Plaintiff and his treating physicians relied on said implied warranty in deciding to use the Cook Celect Platinum filter.
- 72. Cook Defendants, and each of them, breached the above-described implied warranty in that the Filter did not conform to the implied warranty of merchantability and fitness for a particular purpose, as the Filter was and is not safe or effective and it produces serious side effects including, among other things, the injuries sustained by the Plaintiff.
- 73. Prior to, on, and after the dates during which Plaintiff purchased and used the Filter, Cook Defendants, and each of them, were put on notice of the Filter's inability to conform to the implied warranty
- 74. As a direct and proximate cause of Cook Defendants' breach of implied warranty, Plaintiff sustained the injuries and damages described above, for which the solution and ultimate economic loss is yet to be determined.

# COUNT III BREACH OF EXPRESS WARRANTY

- 75. Plaintiff re-alleges and incorporated each and every allegation contained in paragraphs 16 52 as though fully set forth herein.
- 76. Defendants promotional statements concerning the Cook Celect Platinum Filter contained broad, express claims amounting to a warranty that the device was safe and effective and not defective, for the medical purposes for which they were marketed and sold.
- 77. Said warranty is made to consumers, such as Plaintiff, his treating physicians and medical professionals.
- 78. Plaintiff and his treating physicians relied on said warranty in deciding to use the Cook Celect Platinum filter.
- 79. Cook Defendants breached their warranty by offering for sale and selling as safe and not defective, their Cook Celect Platinum Filter was in fact faulty, unsafe and ineffective in respect to the design, manufacture, fabrication and/or marketing.
- 80. As a direct and proximate cause of Defendants' breach of express warranty, Plaintiff sustained the injuries and damages described herein, for which the solution and ultimate economic loss is yet to be determined.

## **PRAYER FOR DAMAGES**

WHEREFORE, Plaintiff, Brian J. Kirkpatrick, prays for relief on the entire complaint, as follows:

a. Judgment to be entered against all Defendants on all causes of action of the Complaint, including but not limited to:

- 1. Pain and suffering;
- 2. Mental anguish in the past and which, in reasonable probability, he will sustain in the future; and,
- 3. Reasonable and necessary medical expenses for treatment received in the past and, based upon reasonable medical probability, the reasonable medical expenses he will need in the future;
- b. Plaintiff be awarded full, fair, and complete recovery for all claims and causes of action relevant to this action;
- c. Plaintiff be awarded all appropriate costs, fees, expenses, and pre-judgment and post-judgment interest on the judgments entered in Plaintiff's behalf; and,
- d. Such other relief the court deems just and proper.

#### **DEMAND FOR JURY TRIAL**

Plaintiff hereby demands trial by jury on all issues.

DATED 12/24/2020.

Respectfully submitted,

#### DALIMONTE RUEB STOLLER, LLP

By:/s/John A. Dalimonte
John A. Dalimonte
MA BBO 554554
75 State Street, Suite 100
Boston, MA 02109
Tel: (833) 443-7529 ext. 104

Fax: (855) 203-2053

Email: john @drlawllp.com

Attorneys for Plaintiff Brian J. Kirkpatrick

## **CERTIFICATE OF SERVICE**

I hereby certify that on 12/24/2020, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing on all CM/ECF registrants.

/s/John A. Dalimonte
John A. Dalimonte